

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NADEZDA STEELE-WARRICK, individually
and on behalf of all others similarly situated,

Plaintiff,

-against-

MICROGENICS CORPORATION and THERMO
FISHER SCIENTIFIC, INC.,

Defendants.

No. 19 Civ. 6558 (VMS)

**SECOND AMENDED
CLASS ACTION COMPLAINT
JURY TRIAL DEMANDED**

Nadezda Steele-Warrick, on behalf of herself and all others similarly situated, and by and through her attorneys, Prisoners Legal Services (PLS) and Emery Celli Brinckerhoff Abady Ward & Maazel LLP, alleges as follows:

PRELIMINARY STATEMENT

1. This is a class action on behalf of thousands of currently and formerly incarcerated New Yorkers who were unjustly punished for false positive drug test results in 2019.

2. Defendant Microgenics Corporation (“Microgenics”), doing business as Thermo Fisher Scientific, is the company with which the New York Department of Corrections and Community Supervision (DOCCS) contracted to provide, install, maintain, and train DOCCS employees on urinalysis analyzers used to conduct drug testing at all DOCCS facilities.

3. Microgenics was required to ensure that the urinalysis analyzers were used in accordance with applicable standards and produced accurate results. Due to its negligent failure to fulfill this basic responsibility, thousands of individuals incarcerated in New York State

prisons received positive drug test results in 2019 even though they did not ingest any illicit substance.

4. When it entered into the contract with DOCCS, Microgenics knew that DOCCS would use positive drug tests to discipline individuals in DOCCS's custody, and that is what DOCCS did. Relying on false positive results generated by Microgenics's urinalysis machines, DOCCS charged and severely punished thousands of individuals for drug use.

5. The punishments DOCCS levied for false positive results were devastating to Class members, who had done nothing wrong and were bewildered by the false accusations.

6. These punishments included, but were not limited to, weeks or months in solitary confinement or keeplock, lost privileges, denial of visitation, and rescission of open parole or conditional release dates. In some cases, individuals were held in prison months for beyond their release dates as a direct result of false positive drug tests.

7. Microgenics and Thermo Fisher Scientific are liable to the individuals currently and formerly incarcerated in New York State prisons who received false positive test results due to their negligent failure to ensure that their drug testing devices and assays were used in accordance with applicable standards and produced reliable test results.

PARTIES

8. Plaintiff Nadezda Steele-Warrick is a 36-year-old woman who resides in Queens County, New York. From 2014 to 2019, Ms. Steele-Warrick was in the custody of DOCCS.

9. Defendant Microgenics Corporation is a Delaware company that is based in Fremont, California, and which specializes in the development, manufacture, marketing, and sale of products relating to clinical diagnostics. Microgenics Corporation is a wholly owned corporate subsidiary of Defendant Thermo Fisher Scientific, Inc. In 2018, Microgenics

Corporation contracted with DOCCS to provide Indiko Plus urinalysis analyzers at 52 DOCCS facilities, and to install, maintain, and train DOCCS employees on those machines.

10. Defendant Thermo Fisher Scientific, Inc. is a Delaware company that is based in Waltham, Massachusetts. Thermo Fisher Scientific, Inc. is the corporate parent company of Microgenics Corporation. Thermo Fisher Scientific markets itself as the manufacturer of the Indiko Plus urinalysis analyzers, as well as the owner of the assays used to conduct drug testing on those machines. Thermo Fisher Scientific is responsible for all FDA submissions made regarding the Indiko Plus urinalysis analyzers and assays used to conduct drug testing on those machines. For purposes of the contract with DOCCS, Microgenics is identified as doing business as Thermo Fisher Scientific.

JURISDICTION AND VENUE

11. This Court has jurisdiction over Plaintiff's claims under 28 U.S.C. § 1332 as Plaintiff and Defendants are completely diverse. The amount in controversy, without interest and costs, exceeds the sum or value specified by 28 U.S.C. § 1332. Jurisdiction over Plaintiff's federal claims is also proper pursuant to 28 U.S.C. § 1331 and 1343(a)(4). This Court also has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

12. Venue in this case is based upon 28 U.S.C. § 1391(b)(3). The Eastern District of New York is the proper venue because it is the judicial district where the Plaintiff currently resides and where Defendants are subject to the Court's personal jurisdiction.

STATEMENT OF FACTS

Defendants Contracted with DOCCS to Provide Urinalysis Analyzers

13. In May 2018, DOCCS issued IFB 2018-06 seeking "reagent rentals of bench top urinalysis analyzer services to be used in its 52 correctional facilities for inmates," with a contract term of September 1, 2018 to August 31, 2023.

14. Defendants submitted a bid in response to the Invitation for Bids on behalf of “Microgenics Corporation Part of Thermo Fisher Scientific.”

15. Microgenics is a wholly owned subsidiary of Thermo Fisher Scientific.

16. Defendants’ bid was submitted on Thermo Scientific letterhead.

17. The web address identified by Microgenics on the bid was www.thermoscientific.com/diagnostics.

18. The two individuals identified by Microgenics as “authorized to negotiate on its behalf regarding all matters pertaining to this bid” were sales representatives with email addresses ending with “@thermofisher.com.”

19. In attachments A and C to its bid, Microgenics submitted marketing materials for Thermo Fisher Scientific relating to its urinalysis systems.

20. In attachment B to its bid, Microgenics submitted literature regarding “ThermoFisher Microgenics Reagent information.”

21. In the bid signature page, Defendants identified “Microgenics Corporation” as the “Legal Business Name of Company Bidding” and stated that Microgenics was “D/B/A – Doing Business As” “Thermo Fisher Scientific.”

22. In September 2018, DOCCS entered into a five-year contract, #CC161458, with Defendants (the “Contract”) to provide Indiko Plus urinalysis analyzers and related services for 52 correctional facilities in New York.

23. The Indiko Plus urinalysis analyzer is an automated benchtop chemistry system that is marketed as a device to conduct urinalysis drug testing.

24. Thermo Fisher Scientific is the manufacturer of the Indiko Plus urinalysis analyzer and the assays used in connection with that machine. It is responsible for the FDA submissions relating to both the machine and assays.

25. The Indiko Plus urinalysis analyzer is sold and distributed by medical distributors across the country, including Microgenics.

26. The Contract required Defendants to conduct onsite training at all 52 DOCCS facilities and to conduct a mandatory master trainer class so that DOCCS could train and certify new testers. Defendants conducted such trainings and certified that DOCCS employees were proficient to operate Defendants' machines.

27. The Contract required Defendants to provide support and maintenance for their urinalysis services, including unlimited 24/7 telephone support; preventative maintenance visits; 24-hour response time; repair, replacement, and maintenance of machines; helpdesk operations; user feedback procedures; and warranties, returns, and exchanges.

28. The Contract required Defendants' employees to testify at disciplinary hearings for incarcerated individuals who received positive drug test results from the Indiko Plus machines.

29. Defendants testified about the professed reliability of their testing at numerous disciplinary hearings in 2019—even when the tests had actually produced false positive results. DOCCS relied on the test results and Defendants' supporting testimony when disciplining incarcerated persons for positive drug tests.

30. The Contract required that Defendants' products be "substantially uninterrupted or error-free in operation." It further required that Defendants warrant and represent that

products delivered under the contract conform to the manufacturer's specifications, performance standards, and documentation.

31. Both Microgenics and Thermo Fisher Scientific were responsible for providing services under the Contract, and both entities negligently provided such services, breaching their duty of care to Ms. Steele-Warrick and putative class members and causing them foreseeable harm.

Defendants Failed to Comply with Applicable Standards and Their Test Results Were Unreliable

32. DOCCS began to use the Indiko Plus urinalysis analyzers provided by Microgenics at DOCCS's facilities in late 2018 or early 2019.

33. As the entities responsible for providing drug testing services in DOCCS' facilities (including machines, assays, services, training, installation, and maintenance), Defendants owed incarcerated persons in those facilities a duty to abide by applicable drug testing standards and to ensure that the testing was accurate and reliable. Defendants breached those duties.

34. Defendants' standards for the Indiko Plus urinalysis analyzers state that the machines should be used as an initial screen only, and confirmatory testing is required to verify any positive result.

35. Despite these standards, Defendants negligently provided products and services to DOCCS knowing that the results generated by the Indiko Plus urinalysis analyzers would be used to discipline inmates without any confirmatory testing.

36. Defendants negligently failed to inform DOCCS of the applicable standards for the Indiko Plus urinalysis analyzers when negotiating the Contract and providing its contracted products and services.

37. Defendants negligently failed to train DOCCS employees on the applicable standards for the Indiko Plus urinalysis analyzers.

38. Defendants negligently testified at disciplinary hearings that the results from the Indiko Plus urinalysis analyzers could be relied on as a basis for disciplining incarcerated individuals, even though Defendants knew that the results were only preliminary screens.

39. Defendants negligently failed to ensure that their products and services were used in accordance with applicable standards even though they had full control over the nature of the use.

40. Defendants knew that positive drug screen results from the Indiko Plus urinalysis analyzers would be used to discipline individuals in DOCCS' custody—without verification by an outside laboratory using gas chromatography or any other verification method—and they did nothing to stop such discipline from being imposed. On the contrary, Defendants' employees supported and endorsed such use.

41. Nothing in the Contract required DOCCS to verify Defendants' drug test results through an outside laboratory using gas chromatography or any other method prior to disciplining incarcerated persons.

42. Not only did Defendants negligently fail to abide by applicable standards, they were also negligent in failing to ensure that the Indiko Plus urinalysis analyzers produced accurate preliminary drug test screens.

43. Contrary to Defendants' representations that their services would be error-free, they failed to ensure that their machines and assays functioned properly, resulting in widespread cross-reactivity issues that caused thousands of false positive results for Suboxone/buprenorphine, AB Pinaca, opiates, and THC.

44. The cross-reactivity issues that ensued were the direct result of Defendants' negligence in their installation, training, and maintenance of the machines.

45. Further, Defendants continued to testify at disciplinary hearings that their test results were reliable even though they should have known that there were serious reliability concerns—especially given the sheer number of incarcerated persons reporting false results.

46. Ultimately, DOCCS determined that the positive results generated by Indiko Plus urinalysis analyzers were so unreliable that it reversed the disciplinary decisions for every positive result for Suboxone/buprenorphine, AB Pinaca, Opiates, and THC generated by the machines in 2019.

47. DOCCS's decision to overturn every positive result for these substances indicates the magnitude of the issue. The problem with Defendants' testing was so widespread that not a single positive finding was reliable enough to discipline putative class members.

48. In January 2020, DOCCS terminated its contract with Defendants for cause, based on Defendants' failure to comply with the terms and conditions of the Contract.

49. DOCCS officials and the New York State Inspector General are both investigating Defendants given the rampant and voluminous unreliable and false positive test results.

50. On February 28, 2020, DOCCS sued Defendants in New York State Supreme Court, County of Albany, alleging that Defendants' equipment, products, procedures, and services were inadequate and deficient, failed to operate according to their intended use, and produced false positive test results.

51. The natural and foreseeable consequence of Defendants' negligent failure to ensure that its products and services complied with applicable standards and produced accurate

results was that thousands of incarcerated persons were punished for false and unreliable positive drug tests.

52. The punishments DOCCS imposed on putative class members included, but were not limited to, weeks or months in solitary confinement; weeks or months in keeplock (where the wrongfully accused individuals were not permitted to leave their cell or dorm area); loss of privileges like recreation, commissary, mail, packages, and phone calls; loss of visitation; loss of good time credit; loss of merit time; loss of an open conditional release date; loss of a parole open date; loss of a preferred work assignment; denial of parole release; denial of conditional release; denial of participation in the Family Reunion Program; removal from a necessary or desired program, such as an education or treatment program; and transfer from a preferred facility or hub. In some cases, individuals who lost good time credit or who had open parole or conditional release dates rescinded were held in prison months beyond their release dates as a direct consequence of the faulty test results.

Plaintiff Nadezda Steele-Warrick Tested Positive for Suboxone/buprenorphine Despite Not Using It

53. Plaintiff Nadezda Steele-Warrick was incarcerated at Albion Correctional Facility (“Albion”), a DOCCS facility, from June 2015 to May 2019.

54. Ms. Steele-Warrick was a model prisoner, with a pristine and unblemished record of good behavior. While incarcerated, she participated in numerous prison programs, obtained her GED, and was employed as a teacher’s assistant. She also taught cardiovascular and mash-up exercise classes at the Albion gym.

55. As soon as she was eligible, after six months at Albion, Ms. Steele-Warrick applied for and received preferred housing on the basis of her exemplary behavior.

56. Preferred housing offers many advantages over general-population housing. In preferred housing, Ms. Steele-Warrick lived with a smaller group of women, making for quieter and calmer surroundings, and she had better access to stoves, showers, and toilets. She obtained a private room, where she had a night stand, closet, radio, safe keeping for her personal belongings, and an overall much greater measure of privacy and quiet.

57. At the same time, when she became eligible after six months at Albion, Ms. Steele-Warrick applied to the Family Reunification Program (FRP), a DOCCS program that allows incarcerated individuals to meet privately and spend overnights with family members. She was admitted to the FRP after approximately seven months on the waiting list.

58. Through the FRP, Ms. Steele-Warrick saw her husband and young son for overnight visits every four weeks. Her husband and son would arrive on Friday mornings and spend two days with Ms. Steele-Warrick in a private setting where they could cook, eat, sleep, and be alone together as a family unit. Her husband and son would depart on Sunday morning.

59. DOCCS protocol requires, as Ms. Steele-Warrick was well-aware, that all individuals participating in the FRP provide a urine sample for drug testing at the following times: (1) between two to ten days prior to an FRP visit; (2) immediately prior to an FRP visit; and (3) immediately following an FRP visit.

60. Pursuant to that protocol, Ms. Steele-Warrick provided a urine sample at approximately 8:30 a.m. on April 14, 2019, following an FRP visit.

61. That same day, at approximately 10:53 a.m., DOCCS officials processed the urine sample on the Indiko Plus urinalysis analyzer using the DRI + CEDIA Drug Testing System.

62. The results came back with a false positive for Suboxone/buprenorphine, even though Ms. Steele-Warrick had not taken that substance, any substance known to trigger a positive result, or any other illicit substance.

63. At approximately 11:20 a.m., as per protocol, DOCCS staff re-tested the urine sample again on the Indiko Plus urinalysis analyzer using the DRI + CEDIA Drug Testing System.

64. Again, the test results indicated a positive result for Suboxone/buprenorphine. Prior to this incident, Ms. Steele-Warrick had never tested positive for any illegal substance, nor had she ever incurred any prison misconduct charges, for drugs or otherwise, during her entire period of incarceration.

65. As DOCCS confirmed months later, Ms. Steele-Warrick's test results were a faulty false positive.

Ms. Steele-Warrick Was Unjustly Charged and Sentenced

66. On Thursday, April 18, 2019, a DOCCS correction officer and sergeant came to Ms. Steele-Warrick's room and advised her she was being charged with drug use.

67. When the sergeant and correction officer informed her of the charge, Ms. Steele-Warrick thought at first they were joking, as she knew it was not possible for her to have a true positive result. She quickly learned they were serious when they handcuffed her, walked her out of her housing unit, and confined her in a disciplinary keeplock cell where she remained for 11 days.

68. Individuals assigned to keeplock have limited access to their property, packages, telephones, correspondence, and visitors, and their commissary privileges are suspended, pending a disciplinary determination.

69. Ms. Steele-Warrick felt tremendous shame and humiliation as she was marched away in handcuffs past her peers and friends.

70. Unlike her private room, which had a door she could self-close and open, Ms. Steele-Warrick's keeplock cell was behind locked and secured steel bars. The room had only a locker, sink, and toilet. It did not have the night stand, radio, or closet that Ms. Steele-Warrick had in her private room. Her meals were delivered through a "feed-up slot" in the bars.

71. Ms. Steele-Warrick did not have access to any of her belongings in her keeplock cell. Her first day there, she could not access her toothbrush, shampoo, or soap. Although she eventually obtained those items, she did not have any of her other personal belongings, including her books or magazines.

72. While Ms. Steele-Warrick was confined in keeplock, correction officers emptied out her private room, searching and cataloguing all of her personal belongings and putting most of it in storage.

73. A package of food from Ms. Steele-Warrick's husband arrived while she was in keeplock, and correction officers confiscated all the fresh vegetables and produce, later leaving Ms. Steele-Warrick with only a couple of canned items.

74. Ms. Steele-Warrick was traumatized by her time in the keeplock cell. She was shocked that she had received what she knew had to be a faulty and false positive drug test result and that she had been summarily confined and was facing serious disciplinary charges. She was petrified of the possible punishment she faced and the black mark on her previous unmarred record of behavior. She cried every day, and people around her began to express concerns about her mental health.

75. She even confided in a mental-health counselor that she was feeling depressed due to the false positive result.

76. Ms. Steele-Warrick faced a formal disciplinary hearing for her charge of alleged drug use. The hearing took place over three separate days while DOCCS continued to hold Ms. Steele-Warrick in a keeplock cell.

77. Ms. Steele-Warrick pleaded not guilty to the charge. She testified at the hearing that she did not ingest any substances containing Suboxone/buprenorphine. Her husband testified that he had not delivered any illegal substances to Ms. Steele-Warrick in the DOCCS facility, and she submitted medical documents from her husband's doctor explaining that the false positive result may have been triggered by a medication he had been prescribed.

78. Despite her testimony, the testimony of her husband, and her husband's medical records, the DOCCS hearing officer found Ms. Steele-Warrick guilty of drug use, relying on the fact that the "test result forms were found to be credible and truthful."

79. Ms. Steele-Warrick was sentenced to 11 days in keeplock (which was equivalent to her time served therein) and thirty days loss of recreation, packages, and commissary privileges. She lost the coveted preferred housing she had previously earned and enjoyed, and was moved back to general population dorm housing.

80. As a result of her sentence, Ms. Steel-Warrick lost her eligibility for the FRP program.

81. Originally, Ms. Steele-Warrick was told that the thirty-day loss of privilege portion of her disciplinary sanctions included her eleven days in keeplock. But when she was given her final paperwork, it stated that the thirty days did not begin to run until the time that she was released from keeplock status. Because Ms. Steele-Warrick's maximum expiration date was

May 22, 2019, she was released from DOCCS custody before her disciplinary sanctions were fully satisfied.

82. The disciplinary disposition, sanctions, and other resulting consequences were devastating for Ms. Steele-Warrick. She felt much less safe and secure in general population housing, where she lived in a large, crowded, open dormitory-style room with about sixty other women. Compared to her private room in preferred housing, it was much noisier, more dangerous, and difficult to access simple amenities like toilets, showers, and the kitchen. She had no privacy, little real personal space, and had trouble sleeping. Some of her personal items were stolen by other individuals.

83. Due to her loss of recreation privileges, Ms. Steele-Warrick was no longer able to go to the gym or serve as a gym class instructor. She was restricted to her dormitory and the mess hall, except for a limited time when she was permitted to go outdoors.

84. Worst of all, Ms. Steele-Warrick was denied her last FRP visit with her husband and son, which was scheduled to occur in May before her release. Because of ongoing immigration proceedings in which she faced possible removal from the United States, Ms. Steele-Warrick did not know what would happen to her when she was released from DOCCS custody. She feared that she would be detained by Immigration and Customs Enforcement (ICE) or even deported. The previously scheduled and much anticipated and desired May 2019 FRP visit was the last time she knew for certain that she would see and spend personal and private time with her husband and son. When the FRP visit was cancelled as part of and because of her wrongful disciplinary sanction, Ms. Steele-Warrick feared that she may never see and spend real time with her family again.

85. Ms. Steele-Warrick also worried about the possible adverse effects of her drug charge on the course and outcome of her immigration proceedings. To enhance her chances of being permitted to remain with her family in the United States, she needed to demonstrate that she was not a dangerous person or a flight risk. The false drug charge posed a reasonable threat to those efforts and potential outcome.

86. The mental and emotional adverse effects of Ms. Steele-Warrick's disciplinary disposition and sanctions cannot be understated. She had worked tirelessly and successfully to become and remain a model prisoner and get her life back on track, and it felt like her world was crashing down due to incomprehensible and unfair circumstances outside her control. She kept thinking, "why is this happening to me?" and she cried to God for answers.

87. On May 22, 2019, Ms. Steele-Warrick was released from DOCCS custody to post-release supervision.

88. In September 2019, Ms. Steele-Warrick's disciplinary hearing result was overturned because of the false positive Suboxone/buprenorphine result.

89. DOCCS informed Ms. Steele-Warrick and other putative class members that the false positives were the result of a "cross reactivity" issue relating to the Indiko Plus urinalysis analyzers.

90. Even before Ms. Steele-Warrick tested positive for Suboxone/buprenorphine, she heard about other prisoners in the FRP program receiving false positive results.

91. For example, Ms. Steele-Warrick's friend received a false positive result and was handcuffed in front of her family during an FRP visit and sentenced to sixty days in solitary confinement. She also heard of another elderly woman in another housing unit who tested positive, even though everyone believed the result was likely false.

92. Even before Ms. Steele-Warrick had a false positive result, correction officers told her that they believed something was wrong with the machines.

CLASS ACTION ALLEGATIONS

93. Ms. Steele-Warrick brings this action under Rule 23(b)(3) of the Federal Rules of Civil Procedure on her own behalf and on behalf of a class of all persons similarly situated.

94. Ms. Steele-Warrick is just one of thousands of individuals wrongly and unjustly punished as a result of Defendants' negligent failure to ensure that its tests were used in accordance with applicable standards and produced reliable results.

95. Plaintiff seeks to represent a class consisting of all persons subjected to the Defendants' unreliable testing devices and services provided under the contract and who received positive drug test results generated by Indiko Plus urinalysis analyzers while in DOCCS custody in 2019 and subsequently had those positive drug tests reversed.

96. The members of the Class are too numerous to be joined in one action, and their joinder is impracticable. Upon information and belief, the class is comprised of thousands of individuals.

97. Common questions of law and fact exist as to all Class members and predominate over questions that affect only the individual members. These common questions of fact and law include, but are not limited to: (1) whether Defendants were negligent in providing Indiko Plus machines that generated false positive results to DOCCS' facilities; (2) whether Defendants were negligent in failing to ensure that its products and services were used in accordance with applicable standards; (2) whether Defendants negligently trained DOCCS corrections officers regarding the applicable standards for using their machines; (3) whether Defendants negligently testified that its machines were reliable for purposes of issuing discipline, when they knew that they should be used as a preliminary screen only; (4) what precautions Defendants took to ensure

that Indiko machines were running in accordance with applicable standards; (5) what disciplinary actions DOCCS took against Class members after Class members received false positive drug testing results; and (6) what damages should be awarded to redress the harms suffered by Class members.

98. Defendants' actions and the claims alleged in this Complaint are common to all members of the Class.

99. Plaintiff's claims are typical of those of the Class. Plaintiff received a false positive drug test result for Suboxone/buprenorphine in 2019 due to a test on the Indiko Plus testing apparatus while she was in DOCCS custody and she was subjected to disciplinary sanctions and various other direct adverse consequences as a result.

100. The legal theories on which Plaintiff relies are the same or similar to those on which all Class members would rely, and the harms suffered by her are typical of those suffered by all the other Class members.

101. Plaintiff will fairly and adequately protect the interests of the Class. The interests of the Class representative are consistent with those of the Class members. In addition, Plaintiff's counsel are experienced in class action, civil rights, and prison-related litigation.

102. Plaintiff's counsel know of no conflicts of interest among Class members or between the attorneys and Class members that would affect this litigation.

103. Use of the class action mechanism here is superior to other available methods for the fair and efficient adjudication of the claims and will prevent the imposition of undue financial, administrative, and procedural burdens on the parties and on this Court, which individual litigation of these claims would impose.

104. This class action is superior to any other method for the fair and efficient adjudication of this legal dispute, as joinder of all Class members is impracticable. The damages suffered by members of the Class, although substantial, are small in relation to the extraordinary expense and burden of individual litigation and therefore it is highly impractical for such Class members to attempt individual redress for damages.

105. There will be no extraordinary difficulty in the management of this case as a class action.

**ADDITIONAL FACTUAL ALLEGATIONS FROM DISCOVERY IN SUPPORT OF
NEW CAUSES OF ACTION IN THE SECOND AMENDED COMPLAINT**

Drug-of-abuse Testing Procedures

106. DOCCS has carried out urinalysis testing on individuals incarcerated at its facilities for decades, using different forms of testing services.

107. DOCCS's policies and procedures regarding testing of urine for drugs of abuse have changed over the years in response to the different products and services provided by third-party providers of urinalysis testing services.

108. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has tailored its testing regulations pursuant to the representations it has received from the third-party providers of testing services as to the accuracy and reliability of those testing services.

109. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has chosen so-called immunoassay testing services on the basis of the belief that those testing services do not require any specialized knowledge, expertise, or verification, and can be carried out by correctional officers without advanced technical supervision.

110. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has relied on employees from the providers of testing services to install and maintain testing systems, and to provide all fixed and consumable materials required for such testing.

111. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has relied on employees from the providers of testing services to evaluate any unexpected or unexplained results from those systems, to diagnose any concerns or failures with the systems, and to remediate all such issues.

112. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has relied on employees from the providers of testing services to respond to customer service questions regarding the operation, maintenance, and reliability of the supplied testing services.

113. “If [a DOCCS] facility has [a] urinalysis testing apparatus . . . [t]he individual performing the urinalysis testing shall have been appropriately trained in the use of the testing apparatus and shall precisely follow procedures recommended by the manufacturer for the operation of the testing apparatus.” N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.4(f)(1)(iii).

114. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has relied on trainers from the providers of testing services to train its staff on the mechanical task of collecting and testing urine to insert into immunoassay machines, as well as on the mechanical tasks of storing and using the reagents and assays used in these testing services.

115. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has relied on trainers from the providers of testing services

to train its staff on reading the results from the testing systems in order to determine whether or not an individual had consumed a drug of abuse.

116. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has relied on trainers from the providers of testing services to train its staff to identify when a positive test result requires a second test on the same machine and assay.

117. In the years urinalysis has been used in New York State correctional facilities, DOCCS has been aware that individuals who take certain medications, consume certain foods, or use certain toiletries may test positive for drugs of abuse when tested on urinalysis systems.

118. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has relied on trainers from the providers of testing services to train its staff to identify when a positive test result may not be accurate, even after a second test.

119. Prior to imposing discipline upon an inmate for drug use based on test results, DOCCS holds a disciplinary hearing. *See* N.Y. Comp. Codes R. & Regs. tit. 7 § 253.6. At such a hearing, DOCCS may use an inmate's positive urinalysis result as evidence of the inmate's illicit use of the drug indicated by presenting, *inter alia*, "any printed documents produced by the urinalysis testing apparatus" and the appropriate Statement of Scientific Principles and Validity of the Testing Apparatus "if the facility has urinalysis testing apparatus." N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.5(a)(1).

120. If any incarcerated individual receives a positive urine drug screen and reports taking medication at the time the sample was obtained, DOCCS must conduct an "inquiry . . . to

medical personnel as to what medications the inmate has received in the past month which may lead to a positive result.” N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.4(d)(2).

121. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has relied on trainers from the providers of testing services to train its staff on when and how disciplinary officers must contact medical providers to identify the medications tested individuals have been using.

122. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has relied on the providers of testing services to provide pharmacists, doctors, nurses, hearing officers, and other individuals involved in the care and supervision of incarcerated individuals with comprehensive and complete lists of substances that may “cross-react” and thereby cause positive test results (“Lists”). These Lists are sometimes included in product inserts.

123. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has relied on the providers of testing services to provide Lists that accurately and completely describe cross-reactivity concerns, including by identifying any areas of scientific uncertainty.

124. On information and belief, in the years urinalysis has been used in New York State correctional facilities, DOCCS has not independently evaluated whether the Lists are accurate, up-to-date, or comprehensive.

125. On information and belief, in the years urinalysis has been used in New York State correctional facilities, providers of testing services have been put on notice that DOCCS will not independently evaluate whether the Lists are accurate, up-to-date, or comprehensive, and

that DOCCS relies on the providers to provide current and complete information regarding any areas of scientific uncertainty in how the testing services perform.

126. On information and belief, in the years urinalysis has been used in New York State correctional facilities, providers of testing services have known that individuals who receive two positive screening results are subject to discipline, including, *inter alia*, loss of privileges, restrictive confinement, removal from programs, loss of good time, and denial of or otherwise interference with parole and eligibility for earned early release from incarceration.

127. On information and belief, in the years urinalysis has been used in New York State correctional facilities, providers of testing services have known that two positive screening results, in practice, are in almost every case sufficient evidentiary basis for the imposition of discipline, unless providers identify specific substances that cross-react or identify areas of scientific uncertainty or disclose failures in the testing system.

128. On information and belief, in the years urinalysis has been used in New York State correctional facilities, providers of testing services have known that testimony from incarcerated individuals that they had not, in fact, ingested drugs of abuse does not, in almost any case, result in being found not guilty in such disciplinary proceedings, even if DOCCS staff might otherwise have doubts as to the guilt or innocence of the tested individuals.

129. On information and belief, in the years urinalysis has been used in New York State correctional facilities, providers of testing services have known that testimony from medical professionals about concerns that non-controlled substances ingested by incarcerated individuals and their loved ones may have caused inaccurate or unreliable results are almost never sufficient basis to prevent imposition of discipline, unless the relevant substances are listed on the Lists.

130. Defendants were aware of the facts alleged in paragraphs 106–129 at the time they sought to secure testing services contracts from New York State and during the pendency of the contract they did secure.

Testing Services Prior to 2016

131. For several years prior to 2016, DOCCS secured testing services from Siemens AG or one of its medical-focused subsidiaries (“Siemens”).

132. By 2016, DOCCS did not have a formal long-term contract with Siemens, but rather engaged in month-to-month ordering of products.

133. Siemens provided DOCCS with its Syva and Viva branded testing services, which use an Enzyme-Multiplied Immunoassay Technique (EMIT) to detect drugs of abuse.

134. On information and belief, EMIT testing had been used at DOCCS facilities for at least thirty years.

135. On information and belief, Siemens worked with DOCCS to update and craft policies and procedures regarding testing in light of the EMIT testing services it provided, recognizing and communicating concerns regarding cross-reactivity and unreliability.

136. At some point prior to 2016, DOCCS officials approached Siemens to ask that Siemens provide representatives who would testify as to the functioning and reliability of testing services during disciplinary hearings.

137. Siemens, for a period, made its employees available for providing such testimony.

138. Siemens, however, determined that it could not continue to provide such testimony regarding the reliability or accuracy of testing results at disciplinary hearings and informed DOCCS of that decision.

139. For several years, the key client contact between DOCCS and Siemens was Brenda Collum, who was employed by Siemens. On information and belief, Collum had

developed close working relationships with several employees of DOCCS due to their long-standing interactions in the provision of drug testing services.

Defendants Approach DOCCS to Change Providers in Late 2015

140. In November 2015, Brenda Collum left Siemens and obtained employment with Defendants. On information and belief, she did not sign a non-compete or non-disclosure agreement with Siemens.

141. As the key client contact at Siemens, Collum was aware of DOCCS's interest and desire in obtaining testimonial services and was aware of the prices Siemens charged DOCCS and the services it was willing and unwilling to provide.

142. As soon as she started her new job, Collum emailed Lt. Corey Bedard at DOCCS from her new email address @thermofisher.com and suggested that DOCCS consider abandoning the Siemens EMIT test and use Defendants' Cloned Enzyme Donor Immunoassay (CEDIA) services instead.

143. CEDIA and EMIT tests are similar in that they are both immunoassays; but they are manufactured in different ways, have different chemical compositions, have different technical specifications, have different output options, and can provide different results.

144. On information and belief, DOCCS had never before used CEDIA tests to test for drugs of abuse.

145. CEDIA tests, even if they provide positive results, require confirmation by gas chromatography and mass spectrometry.

146. On information and belief, prior to 2016, there had been no peer-reviewed scientific studies that approved of using CEDIA testing systems, without confirmatory testing, to impose discipline on incarcerated individuals.

147. On information and belief, prior to 2016, no correctional or penal institution in the United States, whether federal, state, or local, used CEDIA testing systems to impose discipline for drug of abuse charges without first requiring confirmation from a more accurate and reliable testing system.

148. Collum represented to Bedard that Defendants' testing systems are "just like EMIT," but the "[d]ifference here is, these Microgenics reagents are the reagent [*sic*] used by the Federal Courts!" "Also, AK AND Alabama state prison systems (to name 2 of the largest)."

149. Collum told Bedard: "You know my abilities to help you with your drug testing program. Now, I have the backing to help you make better choices to meet all your needs including Admin. Hearings as well as a much better financial option."

150. During late 2015 and early 2016, Collum was supervised by, *inter alia*, Larry Wilkie ("Eastern US Regional Sales Manager") and Brett Richards ("National Sales Manager"); and she collaborated with Kim Mulcahy ("Marketing Product Manager"), who provided Collum with scientific and operational data on the CEDIA tests.

151. On information and belief, each of these individuals was aware of Collum's approach to DOCCS, her prior knowledge of DOCCS's contract with Siemens and the Siemens limitations on providing testimony at disciplinary proceedings, and approved of her efforts to convince DOCCS to switch to using Defendants' testing systems and services.

152. Richards and Wilkie, in particular, were each aware of Collum's approach to DOCCS and were involved in the day-to-day negotiations over how Defendants would persuade DOCCS to abandon the Siemens relationship and retain the services of Defendants.

153. On information and belief, Richards, as the direct supervisor of Wilkie and Collum, was involved in communicating details of these negotiations to his superiors and other officials at Defendants.

154. Between December 2015 and March 2016, Wilkie and/or Collum travelled to New York on more than one occasion to meet with Bedard in person. Richards offered to accompany them because [REDACTED]

Defendants Develop a Tailored Proposal for DOCCS

155. In January 2016, Bedard wrote to Collum and Wilkie asking for a quote from Defendants for their services.

156. Multiple staff members who worked at Defendants, including some individuals who have publicly identified themselves as employed by Defendant Thermo Fisher Scientific Inc., provided input into the proposal in early 2016. In particular, they discussed methods by which they could reduce the cost of providing services to DOCCS and discussed resource concerns regarding providing administrative hearing testimony.

157. Notably, when Defendants sought to bid for this contract in late 2017, these February 2016 discussions were circulated among John Vernasco, Vice President, Commercial Operations; Bill Pyron, legal counsel; and David Hissong, who is publicly identified as the Vice President and Deputy General Counsel of Defendant Thermo Fisher Scientific Inc.

158. While Defendants were preparing their quote for DOCCS, DOCCS asked Collum about Defendants' ability to provide expert witnesses for court proceedings and Defendants' experience in doing administrative hearings previously. On March 6, 2016, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

159. Collum tried to assuage Wilkie's concerns by explaining that experts would only be needed on rare occasions and that she had "a great deal of experience on" administrative hearings and could assist. Collum is not a scientist and knew at this point that Siemens had refused to provide administrative hearing testimony to DOCCS. Later, DOCCS officials would testify that "one of the reasons for changing providers was because [Defendants would] provide testimony and the previous vendor would not."

160. Defendants provided DOCCS with a proposal in March 2016. On information and belief, at least Richards, Wilkie, Collum, Mulcahy, Humaira Saya, Michael Schwartz, Triffany Chung, Gino Gonnelli, Douglas Berg, and Angela Miller provided input into the content of this proposal. Wilkie and Collum sought to meet with Bedard in person to discuss it.

161. Defendants' proposal repeated Collum's representation that Defendants' testing system was used in many correctional systems, met stringent accuracy standards from such facilities, and that Defendants would provide administrative hearing support. Defendants submitted this proposal and made such representations even though they were aware that DOCCS would not carry out confirmatory testing using more accurate methods, despite the proposal itself noting the importance of such confirmatory testing.

162. In April 2016, Defendants wrote to DOCCS with proposals to include assays for testing synthetic cannabinoids, even though research scientists at Defendants were still evaluating such assays. In an attempt to bolster Bedard's ability to advocate for Defendants'

products with Bedard's superiors at DOCCS, Collum asked her colleagues, including Mulcahy, Richards, and Lakshmi Anne, to provide preliminary analyses and summaries, including on issues of cross-reactivity and the professed superiority of Defendants' product over Siemens's.

163. In May 2016, Bedard asked Collum to comment on the "efficacy" of Defendants' system and how it compared to gas chromatography and mass spectrometry. In follow up emails, he sought confirmation from Collum on the equivalence of the EMIT and CEDIA tests. DOCCS thus relied on the data on efficacy provided by Defendants. Collum provided summaries but did not identify any scientific uncertainty, any details regarding cross-reactivity, or any disclaimers regarding the need to carry out gas chromatography and mass spectrometry.

164. Instead of providing full transparency on the scientific uncertainty and limitations of their tests, in July 2016, Defendants provided DOCCS with references in several other correctional jurisdictions and facilities, without disclosing whether or not those facilities used gas chromatography and mass spectrometry testing as well.

165. In August 2016, Mulcahy and Anne produced a draft document comparing EMIT and CEDIA testing systems to be sent to DOCCS. Richards provided feedback regarding whether the presentation to DOCCS was to be [REDACTED] Mulcahy stated that she had [REDACTED]

[REDACTED]

[REDACTED]

166. Internally, in November 2016, scientists at Defendants informed Collum and Wilkie that [REDACTED]

[REDACTED] On information and belief, Collum did not inform DOCCS of this limitation and caveat. Instead, she told her colleagues that DOCCS repeated all positive results and that using the

experimental assay at DOCCS would give Defendants data on how well their assays functioned.

167. In a meeting on December 1, 2016, several employees of Defendants discussed the pros and cons of proceeding with the DOCCS opportunity. They identified it as [REDACTED]
[REDACTED] They acknowledged that DOCCS would [REDACTED]
[REDACTED] In other words, Defendants knew that there would be no backstop to checking the accuracy of their own testing system's scientific reliability before DOCCS's initiation of disciplinary charges and proceedings against and imposition of disciplinary sanction upon incarcerated individuals, but decided to go ahead based on the financial size and value of the contract.

168. On December 5, Mulcahy wrote to Wilkie stating that, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

169. Defendants installed a test machine at a DOCCS facility shortly thereafter, to test side-by-side with the existing Siemens system. Collum told her colleagues that [REDACTED]
[REDACTED]

170. Defendants trained several DOCCS staff on the operation of their testing system. On information and belief, Siemens was unaware of this comparison being carried out.

171. Starting in January 2017, DOCCS raised concerns with Defendants that it was getting incongruous results from Defendants' system. Some samples tested positive on the Siemens, but negative on Defendants' system. Others tested positive on Defendants' system but negative on Siemens, apparently due to cross-reactivity issues. Defendants investigated the issue and reported it was due to their supplying a form of Buprenorphine assay (BUP I) that had a

heightened risk of false positives. To correct this issue, Defendants offered to provide an updated version of the assay that would not cause these issues. That updated assay, known as BUP II, generated a false positive test for Plaintiff in 2019.

Defendants Seek a DOCCS Contract in 2017

172. On February 17, 2017, DOCCS issued a Request for Information, seeking information on new technology for urinalysis in order to develop an Invitation for Bids. On information and belief, Siemens had not been aware that DOCCS was seeking new technology or was dissatisfied with its testing services.

173. In July 2017, Mulcahy wrote to her colleagues that [REDACTED]

[REDACTED]

[REDACTED] She stated that, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Wilkie did not mention the regulatory and scientific requirement that any positive tests on CEDIA tests had to be confirmed with more accurate methods.

174. Three vendors responded to the February 2017 RFI, including Defendants. Bedard forwarded Collum informational emails he had received about the forthcoming bidding process.

175. DOCCS issued IFB 2017-14 on October 31, 2017, based in part on the

information received from Defendants. Siemens, Defendants, and Alere submitted bids.

176. Defendants' bid was more than 30% less than their competitors. DOCCS wrote to Larry Wilkie to ask how Defendants could underbid their competitors by such a large margin. Wilkie responded that "Thermo Fisher Scientific Inc. is the world leader in serving science" and that the company's global reach "allows our company certain economies of scale others don't have." Wilkie further represented that since Thermo Fisher Scientific Inc. "also manufacturing [sic] our own instruments, unlike other vendors who are selling instruments made by companies they do not own," it could "deliver a unique value proposition for our customers." Defendants thus "responded to the bid with full understanding of what is required" and Defendants "have full company support in meeting your needs for the full term."

177. Defendants were tentatively awarded the contract pursuant to their 2017 bid.

178. In January 2018, Siemens challenged the bidding process and the award of the bid to Defendants. The Office of the State Comptroller investigated the bidding process and found that, due to "flaws," the IFB and Defendants' tentative award would have to be cancelled. It was subsequently cancelled.

Defendants Submit a Materially Identical Bid in 2018 and Amend DOCCS Policies on Urinalysis Testing

179. As alleged in paragraph 13 above, in May 2018, DOCCS issued IFB 2018-06, which was a re-bid of IFB 2017-14, with minimal differences.

180. Defendants submitted a bid in response to this IFB that was in relevant part identical to their bid in 2017, albeit with different pricing proposals.

181. In August 2018, Collum wrote to DOCCS to ask for updates on Defendants' bid because she was feeling "a lot of pressure coming down from the top on this bid."

182. In September 2018, DOCCS entered into Contract #CC161458 (the Contract).

On information and belief, DOCCS's decision to enter into this Contract with Defendants was identical to their decision to tentatively award Defendants a contract in 2017.

183. As part of the Contract, Defendants agreed to indemnify DOCCS for any claims it may face resulting from faulty testing services.

184. In late October 2018, Bedard shared an editable draft of DOCCS Directive #4937 regarding urinalysis testing with Collum, soliciting her edits to the Directive so that it could be conformed to the technical specifications of the Indiko Plus.

185. Collum suggested edits to the Directive to equate EMIT tests to CEDIA tests. She proposed adding to the Directive that "DRI and CEDIA reagents are currently used by the largest reference lab in the country; by the Federal Probation and Parole; Department of Defense; as well as numerous other state prisons; hospitals; drug courts and treatment programs." This edit to the Directive did not acknowledge that, on information and belief, all of these other jurisdictions and institutions use confirmatory testing in addition to CEDIA screening testing.

186. Collum also provided to DOCCS snippets from scientific journals regarding CEDIA testing systems, without noting that Defendants' own standards and uniform federal and scientific requirements mandated a gas chromatography and mass spectrometry confirmatory test before discipline can be imposed. These snippets were identical to those provided to DOCCS in 2016 to induce a perception that the EMIT and CEDIA tests are the same. On information and belief, neither Collum nor anyone else at Defendants provided DOCCS with the underlying scientific papers or data from which the excerpts were drawn, or any other data that would acknowledge the scientific uncertainty of the reliability of Defendants' testing system. In fact, as noted above, in July 2017 numerous employees of Defendants had specifically discussed [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

187. All of Collum's edits to the DOCCS Directive, which carries the force of law and is used in disciplinary hearings to justify discipline, were accepted by Bedard into the final Directive. Bedard informed Collum and Wilkie in November 2018 that "the changes to the Directive do not require Department of State intervention" to become law and that he would place them before the Deputy Commissioner of DOCCS for approval. On information and belief, nobody at DOCCS verified the accuracy of the information underlying Collum's additions and edits to the Directive, and Defendants were aware that there would be no further verification of the accuracy or appropriateness of Collum's amendments to the Directive.

188. Incarcerated individuals in DOCCS custody were disciplined in accordance with, on the basis of, and under the terms of Directive #4937, as amended by Defendants.

Defendants Downplay Reports of Unreliable Testing and Dismiss Concerns Raised by Incarcerated Individuals

189. Defendants began training DOCCS staff and installing equipment at all facilities in early 2019. In January, Collum informed employees who would provide testimony at disciplinary hearings that [REDACTED]

[REDACTED]

[REDACTED]

190. In March 2019, almost as soon as the new system was installed, Collum was informed by DOCCS staff that they were concerned the Indiko Plus only displayed results as positive and negative, without an indication of the concentration of the drug of abuse, as the Siemens testing system had done. Jennifer Booth, who had taken over as the main DOCCS contact for urinalysis testing, confirmed that DOCCS had "always provided the inmate with a

cutoff number and their neg and pos results” because “[t]here needs to be something to backup the results.” Collum informed Booth that it was not likely practicable with the Indiko Plus to provide incarcerated individuals with raw data on the level of drugs detected in their samples, in addition to a positive or negative result.

191. Later that same month, a DOCCS officer wrote to Collum seeking extra manuals for the Indiko Plus in order to provide them to incarcerated individuals facing charges for drug use on the basis of urinalyses for their review. Collum objected and emailed Booth to say it was “completely unacceptable” for incarcerated individuals to have access to extra manuals in the prison library. That same month, the first incarcerated individuals started to flag unreliable test results.

192. By April 2019, several incarcerated individuals, including Plaintiff, were reporting that their positive test results were inaccurate and had to have been inaccurate. DOCCS officials wrote to Booth to ask her help in having Defendants come and visit facilities to “inspect our procedures and verify installation and function of the machine” in order “to address the inmate populations [*sic*] concern re: false positives.” In one case, an individual who had not received any disciplinary reports since December 2010 was found positive and, on information and belief, had his parole hearing jeopardized. However, because “[t]he vendor checked the machine results and calibration and found no deficiencies,” the discipline imposed was upheld on appeal.

193. Booth was informed by DOCCS officials in May 2019 that they had been made to understand, on information and belief by Defendants, that the Indiko Plus was a “better technology,” that it “screen[ed] for more” drugs of abuse, and “so the amount of positives will rise,” but that the people testing positive included those who were participating in the family

reunification program—like Plaintiff—and thus, by implication, were highly unlikely to be taking illicit substances.

194. Booth wrote to Collum and Wilkie to raise a concern that Attica Correctional Facility had seen a number of anomalous results and that DOCCS officers were “requesting someone revisit their facility and check the machine parameters and give an overview to staff on testing procedures to ensure they are being conducted properly.” Booth mentioned that Defendants’ system was giving positive results for synthetic cannabinoids for “[o]lder men with no history of drug use” and that similar concerns were raised at Sing Sing. Booth also raised the concern that, for some assays, Defendants had not provided complete lists for verifying cross-reactivity.

195. Defendants sent an employee to Attica to verify that DOCCS officials were using the testing system properly. After a review of the machine and the officers using the machine, the employee wrote to DOCCS officials and stated there is “no reason to question those results.” His “professional opinion” was that the DOCCS was “performing the drug testing in a manner consistent with our recommendations and that the results generated can be trusted as accurate.”

196. Collum followed up by writing to Booth and assuring her that the positive tests—no matter how anomalous—could not be due to any failures or scientific uncertainty in the testing system. Rather, the anomalous tests were likely because certain drugs had never been tested before and because the new Buprenorphine test “is better [and] more sensitive” than the earlier Siemens machines.

197. Also in May 2019, DOCCS officials informed Defendants that DOCCS needed a statement from the company that calibrating the Indiko Plus only weekly was sufficient to ensure reliability. Siemens, when its testing system was used at DOCCS, had warranted that weekly

calibration on its machines was sufficient. When Defendants installed their testing system at DOCCS facilities, they trained DOCCS officials that weekly calibration of the Indiko Plus was also sufficient. However, Defendants' own internal technical specifications recommended *daily* calibration in order to maintain reliability.

198. In internal emails, several employees of Defendants balked at providing written guidance that weekly calibration was sufficient, asking instead that, if DOCCS absolutely required such guidance, it should only be communicated orally. Despite the fact that their internal scientific standards called for daily calibration, key employees of Defendants involved in the DOCCS contract like Karl Beiser and Vladimira Kuftinec pressured their colleagues to rely on an outdated scientific standard on file to justify weekly calibration. Defendants then provided DOCCS with written material sufficient to justify only weekly calibrations, because the “[c]ustomer disciplinary hearing is dependent” on providing such a statement. New York law requires DOCCS officials to “precisely follow procedures recommended by the manufacturer for the operation of the testing apparatus,” N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.4(f)(1)(iii), and Defendants knowingly manipulated their guidance and recommendations to DOCCS on the proper procedure for the operation of their testing system despite knowing that their guidance was not supported by their internal standards.

199. In June 2019, in response to further concerns about unreliable tests from a DOCCS official, Collum reiterated that “the basic principles for testing within NYS DOC for >17 years has been ...emit x2 only.” She affirmed that the same procedure had to be followed with the Indiko Plus and that officers were not permitted to deviate from it because that procedure had been put into place in Directive #4937, which Collum had helped draft and finalize.

200. Collum also directed that “[i]nmates are not to have package inserts,” even though those inserts were often the only means for incarcerated individuals to identify whether any medications they took could cause cross-reactivity with Defendants’ assays. Upon receiving pushback from an officer that incarcerated individuals—or at least pharmacists—must have access to Indiko Plus inserts in order to identify cross-reactivity, Collum stated that “the pharmacist should only see the XR [cross-reactivity] section where is [sic] says could show up positive.” Moreover, Collum represented that “our package insert doesn’t have anything that cross-reacts at clinically significant [sic] levels.” She assured the DOCCS officer that she understood that “inmates and all their friends try to find out everything they can on this,” but that the inserts, which included information about the need for confirmatory gas chromatography and mass spectrometry testing, was not to be shared with incarcerated individuals. In the same month, Defendants’ employees testified at disciplinary hearings that the Indiko Plus was “highly accurate.”

201. DOCCS continued to express serious concerns about inaccurate and unreliable testing in July 2019. In particular, on information and belief, DOCCS had found that many individuals were testing positive for Buprenorphine who would otherwise not be suspected or expected of abusing that drug, including but not limited to individuals at Eastern Correctional Facility. DOCCS officials called Defendants’ technical support line to get assistance on interpreting test results. Finally, in response to these concerns, Defendants agreed to re-review the list of medications being taken by incarcerated individuals who had tested positive for Buprenorphine. At the same time, however, Defendants’ employees testified at disciplinary hearings that medications taken by incarcerated individuals would not cross-react, even though Defendants had never tested the effect of those medications on the Indiko Plus or as to certain

assays.

202. By late July 2019, DOCCS prohibited Defendants from installing any further assays on the testing system and directed Defendants to start sending some samples for further testing using more accurate methods. DOCCS told Defendants that the Buprenorphine assay appeared to be particularly unreliable and was at least too sensitive. Booth put Defendants on specific notice that “inmate[s] are losing programs and time because of these positive results.” Senior officials at DOCCS began to discuss whether there were systemic issues with Defendants’ testing system.

203. By late August, Defendants had still not provided DOCCS with a reliable solution to the unreliable testing results of which they were on notice. In fact, as they testified to the Inspector General later, Defendants had become aware of at least three additional compounds that would likely cause cross-reactivity but made no effort to update their documentation or inform DOCCS. On information and belief, incarcerated individuals were still subject to discipline during this period.

204. On August 22, 2019, Wilkie provided DOCCS with a list of medications prescribed to incarcerated individuals that could interfere with the Buprenorphine assay. The list was divided into three tabs, showing those drugs that had been tested and were known not to react, those drugs that had not been tested but were thought to “have a higher probability of interference,” and those drugs that had not been tested but “run a lower probability of interference.” Wilkie conceded that the Buprenorphine assay provided to Defendants in 2019 “presumptively appears to be sensitive to medications being prescribed to inmates” and suggested shifting back to BUP I, the assay first offered in 2016–17, which had been found to generate a false positive then. If DOCCS retained the system Defendants had warranted as being

“error free,” Wilkie “recommend[ed] additional training to your pharmacist and key stake holders on cross reactivity.”

205. At no point did Defendants acknowledge that incarcerated individuals had been disciplined on the basis of this unreliable test, and they did not propose any remediation for the wrongful discipline that had been imposed. Instead, they reiterated the misleading statement that “[m]any in department of corrections industry, for example United States Federal Probation System, Department of Defense, hundreds of local state and county facilities,” used Defendants’ systems.

206. In a separate PowerPoint presentation during the same period, Defendants represented to DOCCS that “there are no established cutoffs for synthetic cannabinoids . . . and there are no established regulatory limits.” Yet, Defendants continued to propose DOCCS discipline incarcerated individuals when they tested positive for such drugs on Defendants’ testing system. Internally, at the very same time, Collum and her colleagues discussed an instance in which an incarcerated individual who was being treated for HIV tested positive for AB-Pinaca (a synthetic cannabinoid) and had asked Defendants to testify at his disciplinary hearing. Collum wrote that “of course we have not [*sic*] idea” about cross-reactivity “because that is a cocktail of drugs.” However, on information and belief, Defendants took no steps to intervene and prevent this individual from being disciplined.

207. On information and belief, this was the first time Defendants had provided DOCCS with such detailed information, which confirmed the significant scientific uncertainty in Defendants’ testing system. DOCCS required Defendants to send samples to outside laboratories to confirm suspicious cases and installed the alternative Buprenorphine assay now recommended by Defendants. Some of those samples were found to incorrectly have been

marked as positive on the Indiko Plus.

208. In the months leading up to these admissions, Defendants' employees had testified at disciplinary hearings that no over-the-counter medications would cause a false positive, and they testified in some cases that confirmatory testing was only required to identify how much of a drug of abuse was present in a sample, not to determine whether the sample was in fact positive for the drug of abuse. Such knowingly false testimony, combined with the original deception that positive results from the Indiko Plus were reliable without confirmatory gas chromatography and mass spectrometry testing, led directly to the initiation of disciplinary proceedings and imposition of disciplinary sanctions upon incarcerated individuals, resulting in a variety of adverse consequences and harms.

209. DOCCS officials had a conference call with Defendants on September 4, 2019, "to discuss product performance." DOCCS officials made clear to Defendants that they did not wish to speak to sales personnel, who had carried out the majority of the relationship, but rather to technical experts.

210. By September 11, DOCCS officials began to reverse prison disciplinary dispositions due to a cross reactivity issue with the BUP II assay. When Defendants learned of this, Collum wrote to Vladimira Kuflinec that [REDACTED]

[REDACTED]

211. In November 2019, the New York State Inspector General started to review and investigate the use of Defendants' Buprenorphine testing system in state facilities due to concerns about unreliability. The Acting Commissioner of DOCCS ordered that Directive #4937, which had been drafted in part by Defendants, be amended so that "[a]ll urine samples that test positive following application of our current Thermo Fisher immunoassay tests must be

sent for confirmatory testing by an outside, independent, vendor and no incarcerated individual may be disciplined, nor any other adverse action taken against such individual, for a positive drug test before a positive confirmatory test has been received and the disciplinary hearing concluded.”

212. Defendants had known such confirmatory testing was necessary in 2016, when they first began their efforts to supplant Siemens in its contractual relationship with DOCCS. Yet, as late as December 2019, Defendants’ employees continued to testify at disciplinary hearings that no confirmatory testing was necessary. In December, Gilbert O’Young, a Technical Service Representative of Defendants who participated in numerous disciplinary hearings, sent Collum a draft script for technical support representatives to use when called to testify during disciplinary hearings. Collum responded that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

213. Also in December 2019, the Inspector General, as a result of its investigation, advised DOCCS to consider releasing anyone who was in SHU or keeplock on the basis of a positive test for synthetic cannabinoids. DOCCS ordered confirmatory testing on several samples that had tested positive on the Indiko Plus for such drugs and found that not a single one contained these drugs.

214. A few weeks later, DOCCS cancelled its contract with Defendants and reversed all discipline imposed on incarcerated individuals resulting from and related to Defendants' testing services.

Defendants Acted Under Color of Law

215. As set forth above, and without limitation, Defendants worked with DOCCS in installing and implementing Defendants' Indiko Plus urinalysis testing system. That work included training and, in some cases, supervising DOCCS's personnel using the system, testifying at disciplinary hearings, and providing guidance and input on drafting and implementing the DOCCS's testing directive to be used in disciplining prisoners.

216. Thus, Defendants, at all relevant times, acted under color of law because their actions in instituting and operating a regime of prisoner discipline constitutes a public function and/or because Defendants acted in concert with DOCCS in jointly instituting and operating a regime of prisoner discipline based solely on an unreliable Indiko Plus testing system without confirmatory gas chromatography and mass spectroscopy testing.

**FIRST CAUSE OF ACTION
(Negligence)**

217. Plaintiff incorporates by reference each and every allegation contained in paragraphs 1 through 105 as if set forth fully herein.

218. Plaintiff brings this claim on her own behalf and on behalf of the Class.

219. Plaintiff and the Class received false positive drug test results while in DOCCS' custody, resulting in serious sanctions and punishment, as well as a common and typical series of other adverse consequences, including but not limited to those denoted in paragraphs 5-6 above.

220. Defendants owed a duty to Plaintiff and the Class to ensure that the Indiko Plus urinalysis analyzers were used in accordance with applicable standards and produced accurate

and reliable test results.

221. Defendants breached their duty to Plaintiff and the Class by failing to ensure that the Indiko Plus urinalysis analyzers yielded accurate and reliable test results; entering a contract for use of the Indiko Plus urinalysis analyzers that was inconsistent with applicable standards; failing to train DOCCS employees on applicable standards for using the Indiko Plus urinalysis analyzers; and testifying at disciplinary hearings that the results generated by Indiko Plus urinalysis analyzers could be relied on for discipline, when Defendants knew that the results were a preliminary screen only.

222. Defendants knew that DOCCS was relying on test results from the Indiko Plus urinalysis analyzers to discipline individuals in its custody, and it was reasonably foreseeable to Defendants that their failure to ensure accurate and reliable test results and that the Indiko Plus urinalysis analyzers were used in a manner consistent with applicable standards would result in unjust discipline of those individuals and the naturally foreseeable adverse consequences of such discipline.

223. As a result of Defendants' negligent failure to ensure that the Indiko Plus urinalysis analyzers yielded accurate and reliable results and were used in accordance with applicable standards, Plaintiff and Class members were subjected to serious discipline, including, but not limited to, solitary confinement, keeplock, being held beyond their scheduled release date, and loss of privileges.

224. Because of Defendants' unlawful conduct, Plaintiff and Class members have suffered pain and suffering, mental and emotional distress, humiliation, embarrassment, loss of liberty, and monetary damages.

SECOND CAUSE OF ACTION

(42 U.S.C. § 1983; U.S. Const. Amds. VIII & XIV (Cruel and Unusual Punishment))

225. Plaintiff incorporates by reference each and every allegation contained in the preceding paragraphs as if set forth fully herein.

226. By their actions described hereinabove, in facilitating and enabling, and even actively and substantially encouraging, the imposition and infliction of the disciplinary sanctions and various other deprivations and adverse actions against Plaintiff and Class members on the basis of the faulty and unreliable urinalysis testing process and results, and through their deliberate indifference to the unreasonable risk of exposure to such harms, Defendants subjected Plaintiff and Class members to cruel and unusual punishment, in violation of the Eighth and Fourteenth Amendments to the United States Constitution.

THIRD CAUSE OF ACTION

(42 U.S.C. § 1983; U.S. Const. Amd. XIV (Substantive Due Process))

227. Plaintiff incorporates by reference each and every allegation contained in the preceding paragraphs as if set forth fully herein.

228. By their actions described herein, in facilitating and enabling, and even actively and substantially encouraging, the imposition and infliction of the disciplinary sanctions and various other deprivations and adverse actions against Plaintiff and Class members on the basis of the faulty and unreliable urinalysis testing process and results, Defendants caused to be inflicted unlawful, unjustified, and unwarranted punishments and harms upon Plaintiff and Class members, in the absence of any legitimate penological interest, in violation of the substantive due process rights and protections of the Fourteenth Amendment of the United States Constitution.

FOURTH CAUSE OF ACTION

(N.Y. Gen. Bus. Law § 349)

229. Plaintiff incorporates by reference each and every allegation contained in the

preceding paragraphs as if set forth fully herein.

230. New York prohibits “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state” N.Y. Gen. Bus. Law § 349(a).

231. An individual “injured by reason of any violation of this section may bring an action in his own name to enjoin such unlawful act or practice, an action to recover his actual damages or fifty dollars, whichever is greater, or both such actions.” N.Y. Gen. Bus. Law § 349(h). An award of damages may be increased “to an amount not to exceed three times the actual damages up to one thousand dollars,” if Defendants “willfully or knowingly violated this section.” *Id.*

232. As enumerated above, Defendants violated § 349 of the New York General Business Law by using deceptive acts and practices in the conduct of their business.

233. Defendants’ deceptive conduct had a broad impact on consumers at large.

234. Defendants committed the above-described acts willfully and/or knowingly.

235. Defendants’ wrongful and deceptive acts have caused injury and damages to Plaintiff and Class members.

236. Defendants’ violations include, without limitation, misleading DOCCS to believe that the Indiko Plus system could be used to discipline incarcerated persons without confirmatory gas chromatography and mass spectrometry testing through numerous means, including, without limitation, (a) deceptively touting the use of the Indiko Plus system by other corrections and/or parole departments without noting that those departments did not rely on the results of the Indiko Plus without also conducting confirmatory gas chromatography and mass spectrometry testing; (b) warranting that the Indiko Plus could be used as DOCCS intended when it knew it could not;

(c) drafting, editing, and approving the DOCCS directive that provided for prisoner discipline based solely on positive screening tests from the Indiko Plus without conducting confirmatory gas chromatography and mass spectrometry testing; and (d) maintaining and sustaining Defendants' campaign of deceit by insisting to DOCCS that it should continue to use the Indiko Plus system in order to impose harsh discipline on prisoners without equivocation up to the date that DOCCS canceled its contract with Defendants.

237. As a direct and proximate result of these violations of § 349 of the General Business Law, Plaintiff and Class members were charged with misconduct and subjected to serious discipline, thus suffering compensable harm and entitling them to recover statutory, actual and treble damages, costs and attorney's fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Nadezda Steele-Warrick and Class members respectfully request that the Court enter a class-wide judgment:

- A. Certifying this suit as a class action;
- B. Awarding reasonable and just compensatory, statutory, treble and/or punitive damages to Plaintiff and the Class for the injuries they suffered;
- C. Awarding attorneys' fees and costs; and
- D. Ordering other and further relief as this Court deems just, proper and equitable.

Dated: New York, New York
April 12, 2021

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